



OFFICE OF EMERGENCY MEDICAL SERVICES

Administrative Requirements Manual

EFFECTIVE: 3/12/04 AUTHORIZATION: PAGE: 1 of 2

A/R TITLE: Serious Incident Reporting by Ambulance and EFR Services

SUPERSEDES: 7/18/03

PURPOSE:

To provide further guidance to licensed ambulance and EFR services regarding their reporting obligations under 105 CMR 170.350(B). The new provision of the Department's regulation states the following:

170.350(B): SERIOUS INCIDENT REPORTING

(B) Each licensed service shall file a written report with the Department within five days of other serious incidents that result in serious injury to a patient not ordinarily expected as a result of the patient's condition. A serious injury is one that results in exacerbation, complication or other deterioration of a patient's condition. Such reportable incidents include, but are not limited to, the following:

- (1) Medication errors resulting in serious injury;*
- (2) Failure to provide treatment in accordance with the Statewide Treatment Protocols resulting in serious injury; or*
- (3) Major medical or communications device failure, or other equipment failure or user error resulting in serious injury or delay in response or treatment.*

Reportable incidents may have occurred at the ambulance service or EMS first response service itself, in any of its locations, in the course of responding to a call, at the scene with a patient, or, in the case of ambulance services, in transporting a patient and transferring care to an appropriate health care facility.

The requirements of (B) apply whenever a patient has incurred serious injury as a result of the serious incident, as defined in the regulation. The judgment of whether a serious incident that is reportable has occurred is the licensed service's to make, and will probably require the affiliate hospital or service medical director's input.



A/R 5-600

OFFICE OF EMERGENCY MEDICAL SERVICES
Administrative Requirements Manual

EFFECTIVE: 3/12/04 AUTHORIZATION: PAGE: 2 of 2

A/R TITLE: Serious Incident Reporting by Ambulance and EFR Services

SUPERSEDES: 7/18/03

EXAMPLES OF REPORTABLE SERIOUS INCIDENTS:

Reportable incidents include, but are not limited to, the following:

- Medication errors and omissions, such as inappropriate drug, inappropriate dose, inappropriate rate, inappropriate route, or failure to medicate at all in accordance with the Statewide Treatment Protocols, resulting in serious injury.
- Failure to appropriately assess, initiate or administer care in accordance with the Statewide Treatment Protocols resulting in serious injury.
- Burns caused to a patient (e.g., hot packs, cold packs, defibrillators)
- Inappropriate use of carrying devices (e.g., ambulance cot, stair chair, backboard, etc.) that result in a serious injury to the patient.
- Major medical or communications device failure, or other equipment failure or user error resulting in serious injury. This would include those medical device failures that must be reported to the U.S. Food and Drug Administration pursuant to the Safe Medical Device Act.

REPORTING PROCEDURES

Within five business days of a serious incident causing serious injury to a patient (170.350(B)), licensed ambulance and EFR services must submit a report to the Department, on the Department's form for this purpose. A copy of the applicable trip record and any service incident report generated must be attached. The Department retains the authority to request additional information from the licensed service, either verbally or in writing.